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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 20042705

Application Number: 09/980,620
Filing Date: December 05, 2001
Appellant(s): OZEKI ET AL.

MAILED
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GROUP

Gerald M. Murphy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 20, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-14 and 16-28 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,501,866	KAKUDA et al.	03-1996
H1628 US Statutory	EKANAYAKE et al.	01-1997
Invention Registration		

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

- Claims 1-4 stand finally rejected under 35 U.S.C. §102(b) over Kakuda *et al.* (US Pat. No. 5,501,866).
- Claims 5-14 and 16-28 stand finally rejected under 35 U.S.C. §103(a) over Kakuda *et al.* ('866) as applied to claims 1-4 and further in view of Ekanayake *et al.* (H1628).

This rejection is set forth in prior Office Action filed 06/25/03.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kakuda et al. (US Pat. No. 5, 501,866).

Kakuda *et al.* disclose a caffeine stimulation inhibitor and a method for inhibiting caffeine stimulation comprising theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient, wherein the caffeine stimulation inhibitor is added to beverages and foods (see reference column 2, lines 38-46); abstract and claims. The composition is taught to be particularly useful for people who are hypersensitive to caffeine and/or desire to suppress the action of caffeine (including those who desire to drink tea and coffee without impairing sleep) to allow them to consume caffeine-containing beverages or foods without worry over its effects (col. 2, lines 1-62). Kakuda *et al.* disclose that the theanine may be crude or refined theanine and the theanine content in the caffeine stimulation inhibitor is preferably 10 to no more than 500 times the amount of caffeine ingested (col. 2, lines 47-51). The caffeine stimulation inhibitor is preferably used as an additive of beverages and foods and may also be absorbed in the form of tablets, capsules, granules or syrup (col. 2, lines 63-67). Kakuda discloses a method for inhibiting caffeine stimulation wherein the caffeine stimulation inhibitor is also in powder and liquid form (claims 2 and 4). At column 6, lines 25-29 (claim 11) Kakuda *et al.* disclose a food or beverage product comprising beverages containing theanine in an amount between 10 and 500 times greater than the amount of caffeine contained in said foods or beverages. Kakuda *et al.* also disclose various experiments and studies demonstrating the antagonistic action of theanine (col. 3-5).

Claims 5-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakuda *et al.* (US Pat. No. 5, 501,866) as applied to claims 1-4 above, and further in view of Ekanayake *et al.* (US Statutory Invention Registration H1628).

Kakuda *et al.*, as discussed above, teach a caffeine stimulation inhibitor and a method for inhibiting caffeine stimulation comprising theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient, wherein the caffeine stimulation inhibitor is added to beverages and foods (see reference column 2, lines 38-46); abstract and claims. Kakuda *et al.* teach that the theanine-containing substance is produced by extraction of tea leaves with a solvent, such as water or hot water (which is tea) (col. 2, lines 43-46). The composition is taught to be particularly useful for people who are hypersensitive to caffeine and/or desire to suppress the action of caffeine (including those who desire to drink tea and coffee without impairing sleep) to allow them to consume caffeine-containing beverages or foods without worry over its effects (col. 2, lines 52-62). The caffeine stimulation inhibitor is preferably used as an additive of beverages and foods and may also be absorbed in the form of tablets, capsules, granules or syrup (col. 2, lines 63-67). Kakuda *et al.* disclose various experiments and studies demonstrating the antagonistic action of theanine (col. 3-5).

Kakuda *et al.* is deficient only in the sense that he does not teach sugars, minerals and acids in the caffeine stimulation inhibiting tea composition.

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Ekanayake et al. teach a tea extract (which is tea) composition containing high levels of theanine, various sugars, sweeteners, minerals, acids and flavorants (see reference column 1, line 50 through col. 2, line 64); (col. 3, lines 50 through col. 5, line 64).

The theanine composition contains various *sugars*, such as sucrose, glucose, syrups – refiners' syrup, corn syrup, *maltose* and high maltose syrups and mixtures thereof. Sweeteners include sugars, artificial sweeteners, sugar alcohols and other naturally sweet compounds (col. 3, lines 50-67).

Suitable edible acids include any organic or inorganic acid, such as citric, fumaric, acetic, *tartaric* and the like (col. 5, lines 18-33).

Suitable *metal salts* include alkali or alkaline earth metal salts of citric acid, such as sodium potassium or calcium citrate. Other salts such as potassium tartrate, sodium lactate, sodium hydrogen phosphate and related metal salts can be used (col. 5, lines 34-45).

Flavorants include natural and synthetic fruit flavorings, botanical flavorings and mixtures thereof (col. 4, lines 3-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kakuda et al. with Ekanayake et al. since Ekanayake et al. teach a theanine containing composition comprising various sugars, minerals, acids and flavorings because they could aid in obtaining a product that is less astringent and less harsh in tastes and provides all of the benefits of green tea solid mixtures and similarly, Kakuda et al. teach a composition comprising

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theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient, wherein the caffeine stimulation inhibitor is added to various beverages and foods. The expected result would be a highly effective theanine composition for the inhibitory effects of caffeine.

(11) Response to Argument

Firstly, Appellant argues regarding *Group I – Claims 1-3*, stating, “Kakuda et al. ‘866 says nothing of sleep promotion (or a method of promoting sleep) which is an element that appears in independent claim 1; claims 2 and 3 must also contain the “sleep promoting composition” element. Appellant argues that ‘sleep promotion’ is not the same as ‘suppress[ing] the action of caffeine (including, but not limited to, those people who desire to drink tea and coffee without impairing sleep). Kakuda et al. fails to teach ‘sleep promotion’ but rather only teaches ‘not impairing sleep’ (or the ability to sleep regularly). Kakuda et al. does not disclose or suggest taking theanine in the absence of caffeine as is present in Examples 3 and 4 of the instant written description.”

These arguments are not found to be persuasive. Examiner notes claims 1-3 are composition claims and thus the Appellant’s argument that Kakuda et al. says nothing of ‘sleep promotion’ is not persuasive since this is actually a future intended use limitation, which holds no patentable weight and bears no significance to the claims.

Next, the Appellant argues regarding *Group II – Claim 4*, stating, “Kakuda et al. ‘866 fails to disclose or suggest a ‘method for promoting sleep’ as argued in Group I. The arguments made in Group I also apply here.”

These arguments are not persuasive. As delineated above, Kakuda et al.'s composition comprises theanine as the main active ingredient and can be taken by people who desire to drink, for example, tea and coffee without impairing their sleep. The argument that 'sleep promotion is not the same as suppressing the action of caffeine' is also not persuasive since the reference of Kakuda et al. recognizes counter-effecting the effects of caffeine and caffeine is known to be a stimulant that hinders sleep or is a sleep-disturbing agent. Furthermore, the composition is taught to be particularly useful for people who are hypersensitive to caffeine and/or desire to suppress the action of caffeine (including those who desire to drink tea and coffee without impairing sleep) to allow them to consume caffeine-containing beverages or foods without worry over its effects (col. 2, L. 1-62). The argument that "Kakuda does not disclose a method for promoting sleep' is not persuasive since the issue of 'sleep promotion' is implicit in the teachings of Kakuda et al., because they teach counter-acting the effects of caffeine, which is a well-known sleep disturbing agent. Kakuda et al. recognizes the concept of not permitting the impairment of sleep by utilizing theanine and hence such a concept is also generic to issues argued by Appellant.

Next, the Appellant argues regarding the 35 U.S.C. 103(a) rejection of claims 5-14 and 16-28 stating, "The Examiner has failed to make out a *prima facie* case of obviousness. There is no suggestion or motivation to modify the reference or to combine reference teachings. Although theanine is mentioned in both Kakuda '866 and Ekanayake '1628, the purpose of ingesting theanine enumerated in Kakuda '866 would preclude joining theanine with the composition disclosed in Ekanayake. Appellant

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argues Kakuda et al. has an object to suppress the effects of caffeine whereas Ekanayake '1628 has an object not to suppress the effects of caffeine."

These arguments are not found to be persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Kakuda et al. teach a caffeine stimulation inhibiting tea composition and a method for inhibiting caffeine stimulation comprising theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient, wherein the caffeine stimulation inhibitor is added to beverages and foods (see reference column 2, L. 38-46); abstract and claims. The composition is taught to be particularly useful for people who are hypersensitive to caffeine and/or desire to suppress the action of caffeine (including those who desire to drink tea and coffee without impairing sleep) to allow them to consume caffeine-containing beverages or foods without worry over its effects (col. 2, lines 1-62). Kakuda et al. is lacking in terms of having sugars, minerals and acids contained in the caffeine stimulation inhibiting tea composition. Ekanayake et al. is relied upon for the teaching that is known to incorporate various components such as sugars, acids and flavorants in a composition that also contains theanine as a main ingredient. Ample motivation is

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provided by the art since both references utilize theanine as the active ingredient. Furthermore, Kakuda et al. initially meets the objective of 'sleep promoting' as claimed by Applicants since Kakuda et al. teach that their composition can be suitably taken for people who do not desire to impair their sleep and Kakuda et al. teach counter-acting the effects of caffeine, whereby caffeine is known to hinder sleep. Additionally, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

The Appellant argues regarding *Group III – claims 5-7, 11, 16-18*, stating "Kakuda fails to disclose or remotely suggest sugars, flavoring or tartaric acid. Ekanayake fails to disclose or suggest a method of promoting sleep. Kakuda and Ekanayake cannot render *prima facie* obvious the claims of group III. Appellants submit that the Examiner's motivation for combining the references is inapposite; Examiner says the motivation of adding the ingredients taught in Ekanayake is because 'they could aid in obtaining a product that is less astringent and less harsh in tastes'. Appellants point out that Kakuda specifically points out that theanine can be added to beverages and food without degrading the quality, such as flavour and aroma. Thus, Appellant argues Examiner's motivation for adding sugars, flavorants and other natural products is erroneous. Appellant argues neither Kakuda nor Ekanayake disclose or suggest sleep promotion and there is no reasonable expectation of success since one cannot properly combine Kakuda and Ekanayake. Appellant argues the references fail to disclose or suggest all of the claim limitations."

These arguments are not persuasive. Again, the Examiner notes that although Kakuda does not explicitly disclose sugars, acid and flavorants, Ekanayake resolves this deficiency of Kakuda by disclosing a tea extract composition containing high levels of theanine, various sugars, sweeteners, minerals, acids and flavorants. Kakuda et al. state that theanine can be added to beverages and food without degrading the quality, such as flavour and aroma. Kakuda et al. also teach that the theanine-containing substance is produced by extraction of tea leaves with a solvent, such as water or hot water, which is tea as pointed out before. Ekanayake et al's objective is also to provide tea extracts containing tea solids, including caffeine, amino acids, especially higher levels of theanine, flavanols and polyphenols. Ekanayake et al. disclose that their product is less astringent and less harsh in taste and provides all of the benefits of the green tea solid/caffeine mixtures. It is not believed that the Examiner's motivation for combining the references is erroneous since both references provide for a composition that offers beneficial effects of the theanine extract as well as stability. Moreover, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 107, .5 USPQ2d 1596.

The Appellant argues, "Neither of Kakuda et al. or Ekanayake et al. disclose or remotely suggest 'a sleep disorder' and neither mention the words 'disorder', 'disease' or any other related words. Appellants submit there are many causes of sleep disorders

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and ingesting caffeine is not one of them. Kakuda et al. says nothing of sleep disorders or promoting sleep and thus, Kakuda et al. cannot be deemed to be generic for sleep promotion. Appellant argues Ekanayake et al. does not even mention the word 'sleep'.

These arguments are not persuasive. Kakuda et al. indicates in their teachings that their composition can be taken by individuals who do not wish to impair their sleep. Since, Kakuda et al. teaches a caffeine stimulation inhibiting tea composition, whereby caffeine is a known stimulant that disturbs sleep, one would employ the composition of Kakuda et al. to avoid the hindrance of sleep. Although the secondary reference of Ekanayake et al. does not explicitly recite "sleep" or "sleep disorders" in their teachings, the primary reference teaches counter-effecting caffeine effects to avoid sleep disturbance and thus makes generic the issue of sleep or sleep promotion. The caffeine stimulation inhibitor disclosed by Kakuda et al. is taught to be beneficial to individuals that are hypersensitive to caffeine or to those that desire to suppress the action of caffeine. Furthermore, Ekanayake et al. teaches a similar composition incorporating similar ingredients (i.e., theanine, sugars, acids, flavorants, etc.) as that desired by the Applicant and hence the results obtained would also be quite similar to those of the present invention.

Next, the Appellant argues regarding Group IV – claims 8 and 9 stating, "Because claim 8 was not rejected under 35 U.S.C. §102(b) as being anticipated by Kakuda et al., Appellants submit that the Examiner has implicitly acknowledged that Kakuda et al. does not disclose sleep disorders caused by changes in body rhythm as appears in claim 8. Appellants argue Ekanayake et al. fails to make up this deficiency

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and nowhere is the word 'sleep', 'disorder' or disease mentioned. Appellants submit that neither of claims 8-9 can be rendered obvious by the combination of Kakuda et al. and Ekanayake et al. because neither of these references remotely mention changes in body rhythm, insomnia, vigilance in middle of sleep, or vigilance in early morning."

These arguments are not persuasive. Although Kakuda et al. and Ekanayake et al. do not specifically teach the selective group of sleep disorders (i.e., body rhythm, insomnia, etc.), the Examiner believes the teachings of the art to be generic to the issue of sleep disorders because as noted above, Kakuda et al. at column 2, lines 52-63 teaches that their composition comprising theanine can be used even by those people who desire to drink tea or coffee *without impairing sleep* and not worry over its effects. Moreover it is not deemed necessary that the prior art teach each and every disorder/disease condition associated with sleep, since indeed the primary reference of Kakuda et al. does make mention of the condition of "sleep" in itself and does teach counter-acting effects of caffeine, a stimulant, that causes sleep disturbance. Thus

The Appellant argues regarding Group V – claim 10 stating; "The Examiner has implicitly acknowledged that theanine administered in an amount of from 50 to 100% by weight is not disclosed by Kakuda et al. Ekanayake et al. does not make up the deficiency present in Kakuda et al. and does not disclose any weight percent of theanine relative to the entire composition (i.e., 50 to 100%)."

These arguments are not persuasive. Although the specific range of theanine is not explicitly expressed in the art, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in this art that suitable percentages or amounts could be

determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that such a concentration or temperature is critical. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105, USPQ 233, 235 (CCPA 1955). The prior art teaches that the amount of theanine can be varied (Kakuda et al. col. 6, L. 53-54). Furthermore, the Examiner notes that instant generic claim 1 is silent as to any amounts of theanine contained in the composition.

The Appellant argues regarding Group VI – claims 12-14 and 19 stating “A *prima facie* case of obviousness has not been made. Kakuda *et al.* fails to disclose a mineral and Ekanayake fails to disclose sleep promotion.”

These arguments are not persuasive. A *prima facie* case of obviousness has been properly established since Kakuda *et al.* teach a composition comprising theanine, as its main active ingredient whereby the caffeine stimulation inhibiting composition can be taken by those desiring to suppress the action of caffeine and even by those people desiring to drink tea and coffee without impairing sleep. Although Kakuda et al. is lacking in terms of minerals in the composition, Ekanayake et al. resolves this deficiency by teaching, at column 5, lines 34-45, a theanine composition comprising various metal salts. Both art references employ the same active ingredient, theanine, contained in high levels and the properties imparted by the ingredient (i.e., theanine) would also be

the same therefore. Furthermore, Kakuda *et al.* is generic to the issue of 'sleep promotion'.

The Appellant argues regarding Group VII – claims 20 and 28 stating, "The Group C mice appeared to demonstrate the exact same effects as the mice that were given no theanine but given caffeine (Group B). Claim 28 claims a dosage of 0.2 to 200 mg/kg; the dosage of theanine that is ineffective in Kakuda '866 (174 mg/kg) falls within this range. The dosage of theanine that is effective (1740 mg/kg) falls way outside this range. Thus, Appellant argues, Kakuda appears to teach away from using theanine at a concentration that is claimed in claim 28."

These arguments have been carefully considered but are not persuasive. The argument that the 'Group C mice demonstrated the exact same effects as Group B mice' is believed to be incorrect since Kakuda *et al.* at col. 3, lines 61-64 teach that 'in contrast to Group B, although the amount of spontaneous movement of Group C increased slightly in the early stages of the experiment, *the increase was more inhibited than in Group B*', which means that the effects were not exactly the same as argued by Appellant. Moreover, Kakuda *et al.* at column 4, lines 1-3, teach that 'Group C did *not* demonstrate an increasing trend, with the *amount of spontaneous movement decreasing slightly* in the latter half of the experiment.' By this teaching one would not come to the conclusion that Group C effects were exactly the same as Group B effects, as interpreted by Appellant. Hence, the argument that the 'dosage of theanine of 174 mg/kg is ineffective' is not persuasive since Kakuda *et al.* does teach that the amount of spontaneous activity *decreased* in Group C and does teach a range of 174 mg/kg,

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which is clearly an effective amount that falls within the Applicant's dosage range of 0.2 to 200 mg/kg. Moreover, one of ordinary skill in the art would be entirely capable of determining suitable amounts based on routine experimentation, to obtain the best possible results.

The Appellant argues for Group VIII – claims 21 and 25-27 stating, “Similar to Group V, group VIII also contains disorders (i.e., changes in body rhythm, insomnia, vigilance in middle of sleep and in early morning) in addition to disturbance of restful sleep. Neither Kakuda et al. nor Ekanayake et al. disclose or suggest moderating or ameliorating sleep disorders and neither disclose or suggest sleep disorders and neither disclose or suggest sleep promotion.”

These arguments are again not persuasive. Kakuda et al. and Ekanayake et al. are cited for all that they teach, as pointed out in the prior ‘Grounds for Rejection’ section of this action. Although the art does not recite particular sleep disorders claimed by Applicants, Kakuda et al. teach an effective theanine composition that is clearly generic to the issue of sleep promotion since the reference of Kakuda et al. recognizes counter-acting the effects of caffeine and caffeine is known to be a stimulant which hinders sleep significantly. The prior art teaches theanine compositions that contain the same ingredients (i.e., theanine, sugars, minerals, etc.) in similar amounts and in the same field of endeavour and hence the results and properties imparted by those ingredients would also be similar to those desired by the Applicants, regardless of the particular sleep disorder.

Lastly, the Appellant argues regarding Group IX – claims 22-24 stating, “None of claims 22-24 can be rendered obvious by the combination of Kakuda and Ekanayake because neither reference remotely mentions changes in body rhythm, insomnia, vigilance in middle of sleep or vigilance in early morning.”

These arguments are again not persuasive since, as delineated above, Kakuda et al. teach an effective theanine tea composition that can be taken by those desiring to suppress the action of caffeine and even by those people desiring to drink tea and coffee without impairing sleep and not worry over its effects. The particular sleep disorders claimed by Applicants would be implicit in the teachings of Kakuda et al. since their composition prevents the hindrance of sleep. Ekanayake et al. is cited for their teaching of a beneficial theanine composition and also teach various additives of sugars, minerals, acids and the like. Since the prior art clearly teaches formulations comprising similar ingredients in similar amounts as those instantly claimed, it is believed that a *prima facie* case has been properly established. Thus the Examiner finds instant claims 1-4, 5-14 and 16-28 to be unpatentable over the art of record.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Humera N. Sheikh - Group 1615



hns

June 1, 2004

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